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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,503

01/28/2004

Dan E. Fischer

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06/25/2008

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EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/766,503	Applicant(s) FISCHER, DAN E.	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-15 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10,14,15 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response and amendments to claims filed with the office on April 5th 2008 is duly acknowledged.

Claims 11-13 (group II) remain withdrawn from further consideration.

Claim 3 has been cancelled by applicant's current amendment to claims.

Claims 1-4, 6-10, 14, 15 and 28-33 (as currently amended) are examined on their merits in this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-3, 6-10, 14-15, and 28-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitations "**initially non-adhesive** covering", "a **continuous** outer cover", and "to **completely** encapsulate and retain" in claims 1, 14 and 28 do not have support in the as-filed specification. The insertion of these limitations represents a **new concept** because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of "a dry and initially non-adhesive

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covering” that forms “a continuous outer cover of the implant device so as to completely encapsulated and retain the bone growth promoting material within the enclosed space” as currently presented by applicants. There is no exemplified disclosure to support such a new concept. Applicant’s response (see remarks, page 7, 1st and 2nd paragraphs, in particular) fails to provide the basis for these limitations as currently recited in the claims. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of limitations “**initially non-adhesive covering**”, “a **continuous** outer cover”, and “to **completely** encapsulate and retain” is considered to be the insertion of **new matter** for the above reasons.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3, 6-10, 14, 15 and 28-33 (as currently amended) are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al (US 4,863,472; [D]) taken with Silverberg (US 4,755,184; [E]), Levy (US 5,292,253; [A]) and Vyakarnam et al (US 6,306,424 B1; [F]), and further in view of Kenyon et al (US 2,423,707; [A]).

Claims are generally directed to **an implant device** comprising a dry and initially non-adhesive covering comprised of “a water absorbing gelatinizable material” that defines an enclosed space (and which becomes sticky and gelatinous upon contact with water), a “bone growth promoting material”, disposed within the enclosed space defined by the dry covering (as recited in claim 1, as amended), wherein the water absorbing gelatinizable material consists essentially of at least one of gelatinizable gauze, oxidized cellulose, oxidized regenerated cellulose, or gelatinizable cat gut; wherein the dry and initially non-adhesive covering forms a continuous outer cover of the implant device so as to completely encapsulate and retain the bone growth promoting material within the enclosed space (see instant claims 1-3, 6-10, 14, and 15); and wherein the implant device comprises the bone growth promoting material in granular or powder form, and a thickener dispersed among said bone growth promoting material (see specific recitations of claims 28-33).

Tormala et al [D] disclose an implant device comprising “water absorbing gelatinizable material” (a supporting structure suitable to work as a covering/encasing made of materials such as polyglycolide, **cellulose derivatives** or cross-linked **collagen** derivatives such as cat gut/**Katgut**; see Tormala et al, abstract; figures 1-2; columns 3-4; and column 4, lines 17-25, in particular) and a “bone growth promoting material” contained within said gelatinizable material (see Tormala et al, abstract and claims, in particular), wherein the water absorbing gelatinizable material is resorbable or non-resorbable, wherein bone growth promoting material is as specifically recited in instant claim 5 (such as synthetic ceramic powders, or **hydroxyapatite** powder; see column 8, example 2, in particular), wherein the implant device has an elongated sausage-like or pillow like configuration (in the absence of any defined structural

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features/parameters in the claims for such “sausage-like” or “pillow-like configuration; see Tormala et al, figures 1-3 and column 5, 3rd paragraph, in particular), and a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Tormala et al, columns 5-6, in particular). In addition, Tormala et al disclose the fact that one can use or admix resorbable fibers, or polymer to bind (to work as a glue, i.e. used as a **thickener** that can form viscous gel upon contact with water) the bone graft particles together, if used as an additional inner resorbable supporting structure of the powder phase (see column 3, lines 1-2; column 4, last paragraph; and claim 9, in particular). Also disclosed in Tormala et al is the fact that the supporting structure (i.e. the covering) can be made of any shape or size (such as a bag or a flat tube; see abstract, column 6, lines 57-64, in particular) and the covering can be constructed in the form of a **woven or knitted** fibers (see column 5, lines 36-38, and claim 10, in particular).

Silverberg [E] discloses an implant device comprising “water absorbing gelatinizable material” (suitable to work as a covering material such as a **casing** made from polyglycolide in the form of a mesh, or **collagen or cellulose**; see abstract, summary of the invention, column 3, lines 31-55, and claims, in particular) and a “bone growth promoting material” contained within said gelatinizable material (such as hydroxyapatite; see examples, column 4-5, in particular), wherein the water absorbing gelatinizable material is resorbable, wherein bone growth promoting material is

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hydroxyapatite powder, wherein the implant device has **an elongated sausage-like or pillow like configuration** (see figure 1, in particular) and is gas sterilized prior to surgical applications (see column 5, 1st paragraph, in particular); and a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Silverberg, column 4 and figure 3-5, in particular).

However, the inventions of Silverberg or Tormala et al do not explicitly teach (although, suggest the generic materials such as collagen and cellulose, and derivatives thereof; see discussions above) the “dry covering” (that is initially non-adhesive) to be made of a water absorbing material that becomes sticky and gelatinous upon contact with water (i.e. moisture activated).

Kenyon et al [A] disclose a **gelatinizable gauze** (i.e. a surgical fabric or sponge made of **oxidized cellulose**; see columns 1-2, and claims in particular) to be used as a dressing material on wounds, cuts and the like, wherein the gauze can be resorbable (see column 1, last paragraph, in particular) *in vivo*, or non-resorbable (depending on the amount or extent of oxidization using NO₂ and a halogenated hydrocarbon; see column 2, 2nd paragraph, and examples 1 and 2, in particular), and thus, can be used as a hemostat or as a dressing (in woven or knitted forms; see figures 1-2) for the treatment of the wound.

Therefore, it would have been obvious to a person of ordinary skill in the clinical art to modify the inventions of Tormala et al or Silverberg such that the covering used is made of a water absorbable gelatinizable material such as oxidized cellulose (i.e. a

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gelatinizable gauze made of oxidized cellulose) which is explicitly taught by Kenyon et al for the benefits of having both resorbable and/or non-resorbable properties of the oxidized cellulose material used in the form of a woven or knitted material. Thus, an artisan of ordinary skill in the medical art would have had a clear motivation and a reasonable expectation of success in substituting the “dry covering” disclosed by Tormala et al or Silverberg with the material (i.e. a functional equivalent, such as cellulose derivatives including oxidized cellulose that are known to be gelatinizable upon contact with water or other aqueous materials such as body fluids, and are known to be made in bio-resorbable as well as non-bioresorbable forms) explicitly taught by Kenyon et al for the treatment of wounds that produce bleeding (such as during the removal and filling of tooth, etc.).

However, an implant device further comprising an adhesive such as **fibrin powder** (see instant claims 9-10); or a implant device, which is stored within **moisture-resistant packaging** is not explicitly disclosed by the referenced inventions of Silverberg, Tormala et al, and Kenyon et al.

Levy [A] explicitly discloses the use of **fibrin** with or without collagen (see column 3, lines 24-29, and claims, in particular) to form a protein gel that can be combined with calcium-containing materials such as hydroxyapatite and/or calcium phosphate to prepare an implant used for filling the void or defects for the repair of tooth and bone tissues.

Vyakarnam et al [F] disclose the routine practice of packaging implant materials after sterilization in an appropriate sterilized, **moisture-resistant package** for shipment and use in hospitals and other health care facilities (see column 19, 3rd paragraph, in particular).

Therefore, given the detailed disclosures of the components and the structure of the implant device (as claimed in the instant application) in the above cited prior art references, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the implant device taught by Tormala et al (taken with the disclosure of Silverberg and Kenyon et al) such that it further comprises an adhesive such as fibrin, and is stored within a moisture-resistant packaging as explicitly suggested and demonstrated by the disclosures of Levy and Vyakarnam et al with a reasonable expectation of success in order to provide a gelling component or a glue in the composition as well as to avoid contamination of the implant device during storage (both the limitations are deemed to be routinely practiced in the implantation art).

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir.1989).

Response to Applicant's Arguments

Applicant's arguments filed with the office on April 5th 2008 (as they pertain to the pending claims 1-3, 6-10, 14, 15, and 28-33) have been fully considered but they are not persuasive for the following reasons of record.

Applicant argues the following (see response, pages 8-10):

"A. Tormala et al. is not an Appropriate Reference for Rejecting the Claims Because it Explicitly **Teaches Away** from a Bone Implant Device Having a Covering That Completely Encapsulates the Bone Growth Promoting Material". (refers to col.2, lines 10-59 in Tormala et al)

"B. Tormala et al. and Silverberg are not Properly Combinable Because Tormala et al. **Disparages** the Implant Device of Silverberg." (see response, page 10, in particular)

"C. The Remaining References Fail to Teach or Suggest the Combination of Limitations Recited in the Claims as Amended." (see response, page 11, in particular)

It is noted that as argued by applicant, the prior art reference of Tormala et al does not teach away from a bone implant as claimed because it does provide disclosure wherein "the orifice of the supporting structure can be closed by means of a thin ceramic plate with open porosity through which the bone tissue can grow. The orifice can be closed also by means of a rapidly resorbable film..." (see Tormala et al, column 3, 3rd paragraph, in particular), thereby completely encapsulating the bone growth promoting material within the encasing or supporting structure that can be in the form of " chute-like, box-like, a flat tube, or a bag" (Tormala et al, see column 2, lines 30-38, and column 6, lines 54-64, in particular). Moreover, Silverberg explicitly discloses an implant for use in bone augmentation that includes a "hollow encasing" made of resorbable material that can be filled with a bone growth promoting material, and thus, such implant device would have been obvious to an artisan of ordinary skill in the art at the time this invention was made. In addition, both Tormala et al and Silverberg provide the disclosure for the use of suitable encasing or supporting materials such as cellulose derivatives (for example oxidized cellulose; see discussion above, and the cited prior art Kenyon et al, in particular), therefore, an artisan of ordinary skill in the art would have had motivation to use oxidized cellulose (that has property, depending on the amount of oxidation, of becoming sticky and gelatinous upon contact with water; see discussion for Kenyon et al above) for making an implant device such as claimed.

It is to be noted that applicant has failed to provide the disclosure for the identity (i.e. the oxidation status, or chemical structure, etc.) of the specific oxidized cellulose derivative used in the invention as claimed and the functional properties of which is being argued. In the absence of a clear disclosure of the material used for making the claimed implant, the cited prior art disclosures meet all the limitation of the components used for making and using such an implant for the same purposes as claimed.

Applicant further argues the following (see response pages 11-12, in particular):

"Moreover, it would be contrary to Silverberg to substitute the casing materials disclosed therein with materials such as those recited in claims 1 and 28, which become sticky and gelatinous upon contact with water. The method by which the implant device of Silverberg is implanted involves using a syringe. Col. 4, lines 9-13; Figure 2. "The implant is typically wetted with sterile saline solution prior to installation to facilitate lubrication" (col. 4, lines 13- 15) (emphasis added). Thus, the casing material employed in Silverberg becomes better lubricated when contacted with a saline solution (i.e., water). If one were to substitute the casing material disclosed in Silverberg with a covering material that becomes sticky and gelatinous upon contact with water, it would prevent or inhibit lubrication with water. Instead, wetting the implant device with saline solution would yield an implant device having a sticky and adhesive covering, the very opposite of "facilitate[ing] lubrication" as taught in Silverberg.

In short, substituting the water lubricatable casing material of Silverberg with a material that becomes sticky and gelatinous with water would render the Silverberg device unsuitable for its intended purpose. For this reason, Silverberg **implicitly teaches away** from an implant device having a dry and initially non-adhesive covering comprised of a water absorbing gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water so as to render it adhesive to bone tissue. Because Silverberg implicitly teaches away from the claimed implant device, one of skill in the art would not have substituted the water-lubricatable casing of Silverberg with any of the covering materials recited in claims 1 and 28 as amended (i.e., gelatinizable gauze, oxidized cellulose, oxidized regenerated cellulose,, and/or gelatinizable cat gut)."

Applicant's argument has been fully considered but is not found to be persuasive because Silverberg discloses the use of cellulose as a suitable encasing material (see Fig.1; and column 3, lines 44-48, in particular), and therefore, given the combined disclosures of Tormala et al and Silverberg, an encasing made of a resorbable material such as oxidized cellulose (or a cellulose derivative) would have been obvious to one of ordinary skill in the art. The differences in the functional properties of the encasing material used (lubricatable verses sticky and gelatinous), as argued by applicant is not found to be persuasive as it is taken to be the intrinsic property of the oxidized cellulose itself (in view of the disclosure of Kenyon et al as discussed above).

Applicant's arguments regarding the functional limitations in the claim recited to characterize the encasing materials used for making the claimed implant (see response, pages 13-14, in particular) is not found to be persuasive because such properties are taken to be intrinsic to the compound used for making such encasing as already disclosed in the cited prior art references (see Tormala et al in view of Silverberg and Kenyon et al, in particular), which would have been obvious to an artisan of ordinary skill at the time of this invention was made.

Therefore, the obviousness rejection of record is properly made and maintained.

Conclusion

NO claims are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

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Examiner, Art Unit 1657